Paper No. 68

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT WEINBERG, CLIFFORD TABIN
and SCOTT BRADLEY

Appeal No. 2003-0054
Application No. 08/308,193

HEARD: April 15, 2003

Before WILLIAM F. SMITH, LORIN and SCHEINER, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 93, 99 and 100. Claims 95 and 97, the only other claims pending at the time of the final rejection, have been canceled by an amendment under 37 CFR § 1.116 filed with appellant's Brief (paper no. 62). Claims 93, 99 and 100 read as follows:

93. A nucleic acid probe capable of detecting a single base difference between a nucleotide sequence present in a previously isolated oncogene and a nucleotide sequence present in a corresponding previously isolated proto-oncogene, wherein the single base difference is responsible for conversion of the proto-oncogene to the oncogene and the single base difference is located in a sequence recognized by a restriction enzyme.

99. The probe of claim 93, wherein the oncogene is a human ras oncogene.

100. The probe of claim 93, wherein the human ras oncogene differs from the human ras proto-oncogene in the codon for position 12.

Claims 93, 99 and 100 stand rejected under the doctrine of obviousness-type

double patenting as unpatentable over claims 1-16 of U.S. Patent No. 4,535,058 in view of Wallace.[1]

We reverse the examiner's rejection, but enter a new ground of rejection under the provisions of 37 CFR § 1.196(b).

DISCUSSION

Double Patenting

The present claims are directed to a nucleic acid probe capable of recognizing a single base difference within a restriction site of an oncogene or its corresponding proto-oncogene, while the patented claims are directed to assays "for detecting the mutation of a proto-oncogene to an oncogene" wherein the proto-oncogene or the oncogene is digested "with a restriction enzyme specific for a cleavage site present only in either [the] proto-oncogene or [the] oncogene" (patented claim 1). Wallace describes the effect of single base pair mismatches on the hybridization kinetics of DNA probes to wild-type ΦX174 DNA, and concludes that "[the] system represents a useful model for the study of the effect mismatched base pairs on duplex formation and [thermal] stability" (pages 3543 and 3544).

The examiner's rationale for concluding that the present claims are unpatentable over the patented claims is essentially that "the patent claims [involve] a single base pair mutation and Wallace teaches that when one needs to detect a single base pair mutation one constructs a probe" (Answer, pages 4 and 5).

Without belaboring the record, we will simply say that we agree with appellants to the extent they argue that the claimed "nucleic acid probes . . . are not 'obvious

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[1] Wallace et al. (Wallace), "Hybridization of synthetic oligodeoxyribonucleotides to ΦX174 DNA: the effect of single base pair mismatch," Nucleic Acids Research, Vol. 6, No. 11, pp. 3543-3556 (1979).

variations' of the assays and methods recited in claims 1-16 of the '058 patent" (Brief, page 13), none of which requires a nucleic acid probe of any kind, let alone a probe capable of recognizing a single base difference within a restriction site of an oncogene or its corresponding proto-oncogene. Further, we see nothing in Wallace's study of the thermal stability of single base pair mismatches which would have led one skilled in the art to generate probes with the required functional characteristics.

Accordingly, we reverse the rejection of claims 93, 99 and 100 under the doctrine of obviousness-type double patenting.

NEW GROUND OF REJECTION

Written Description

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: Claim 93 is rejected under the first paragraph of 35 U.S.C. § 112 as lacking an adequate written description of the claimed invention.

In Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir, 1997) (citation omitted), the court stated that,

> In claims to genetic material, [ ] a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. . . . One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. [ ] It is only a definition of a useful result rather than a definition of what achieves that result.

The court recently clarified this position, emphasizing that "[not] all functional descriptions of genetic material fail to meet the written description requirement," for example, "the written description requirement would be met for [a claim] . . . if the

functional characteristic . . . were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." See Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324-25, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

Claim 93, however, is directed to nucleic acid probes, defined solely by their ability to recognize a single base difference within an unspecified restriction site of an unspecified oncogene or its corresponding proto-oncogene. In other words, the claimed genus is defined in purely functional terms, without reference to a disclosed structure. This functional description, without more, does not satisfy the standard articulated in Enzo, and we conclude that the claimed genus is not adequately described as required under the first paragraph of 35 U.S.C. § 112.

CONCLUSION

We have reversed the rejection of the claims under the doctrine of obviousness-type double patenting, and entered a new ground of rejection against claim 93 under the provisions of 37 CFR § 1.196 (b). As a result of action today, claims 99 and 100 are free of rejection.

TIME PERIOD FOR RESPONSE

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196 (b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997) 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196 (b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196 (b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR

§ 1.197 (c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197 (b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136 (a).

REVERSED; 37 CFR § 1.196 (b)

William F. Smith Administrative Patent Judge	)
	) BOARD OF PATENT
Hubert C. Lorin Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Toni R. Scheiner Administrative Patent Judge	)

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